out-of-spec results besides the three we just talked about?

A. Let me just check one location.

For clarity to answer your question, by "repetitive," I think it's the same location failed repeated -- but not repetitively. I think I misstated it. It's the same location failed in several of these batches.

Q. Well, my question is: Do you know of any other batches --

A. Other than these three, no.

MR. MILLER: You have to wait.

Q. And the three that the FDA is referring to are 70148A; right?

A. Uh-huh.

Q. That's a yes?

A. Yes, sir.

Q. 70207A?

A. 7070A (sic), yes, sir. And 70207A, yes, sir.

Q. So in the last paragraph of Page 10 of your report, when you talk about the firm "struggling with the procedure and repetitive failures," these are the only three of which you are aware; correct?

A. Those are the three that I'm aware; in addition to my own experience in how difficult this

task can be.

Q. And the last part of your statement says, "Blend sampling program was ineffective and not predictive of final product quality."

What's the basis for that statement?

A. My basis for that statement is: If you cannot isolate that the blend itself is uniform or non-uniform, this gets back to: Is the sample reliable or not, you cannot assume that the blend is indicative of anything downstream. It gets back to the continuum of the whole structure.

It really gets back to the heart of my first comment, the comment we had about the blend.

On -- in balance, this stuff is -- everything seems right. But if you start to pull things out of context and ask the questions in an investigation, it starts to bring to light a systematic problem that, again, is inferential at best at this stage, Matt, if you know --

Q. But you have to pull it out of context to do that; right?

A. And, again, someone skilled in the art like myself would do that.

Q. So I want to jump ahead just for a moment.

A. Go ahead.

Q. You have looked at all the annual reports which nicely condense and summarize the finished product test data for this product; correct?

A. No, I did not.

Q. You haven't looked at the annual reports?

A. No, sir.

Q. Do you know whether any batch of Digitek, just among the recalled batches, failed finished product testing?

A. I believe one did, sir.

Q. Which one?

A. That I'd have to check.

Q. Just so we are clear. Do you know of a single batch of Digitek that was submitted to the QC testing for its USP testing that failed those tests?

MR. MILLER: Object to form.

Q. And if you know of one, tell me what batch number it was?

A. I can't tell you what batch number it is. I only have a picture of a rejected form. I'd have to go back and dig it out. I know it's not in this pile.

Q. Okay. Well, do you know of any batch that was actually sent to market that failed finished product testing at Actavis?

A. If all -- if all of the parts and pieces are

working together, that should never happen, sir. Right?

Q. Well, you know that each batch is tested; correct?

A. Right, right.

Q. And that there is actual data available; correct?

A. Uh-huh.

Q. So have you looked at the data to see whether any batches failed finished product testing?

A. In the batches I looked at, no. Only the batches I looked at.

Q. Well, let's just start with the recall. Out of the 152 batches that were actually sent through Mylan to pharmacies, did any of them fail final product testing?

A. Not to my knowledge, sir.

Q. And if we tried to do the math, and I haven't done it before today, if we just take the 152 recalled batches, and say that there were 30 blend uniformity -- I'm sorry.

MR. MORIARTY: Let me withdraw that question.

Q. We just take the recalled batches and say that there was one blend uniformity battery for the whole batch, that would be ten samples per batch;

correct?

A. Thirty.

Q. Well, let's just take one set of them, not three deep. You are talking about 1,520 blend samples; correct?

A. For those batches.

Q. Yes. Right?

A. Right, 152 times ten.

Q. And there were three that were out of spec; right?

A. Uh-huh.

Q. That's a yes?

A. Yes, sir.

Q. Each of the three that were out of spec weren't confirmed on retesting; correct?

A. That's correct.

Q. And you think even if those batches were included in the recall set, which we are not sure they are, three out of 1,520 constitutes repeated failures that are predicted -- mean that blend uniformity aren't predictive of final product quality?

A. Absolutely. The reason is because of the uncertainty in doing the sampling.

Q. All right. Did FDA ever actually say that any Actavis batches of Digitek failed blend uniformity

testing?

A. They called it out of specification. They didn't say it failed.

Q. Okay. Did they ever say that any batches of Digitek failed blend uniformity testing?

A. Not that I recall, other than what's here.

Q. If somebody just colloquially -- colloquially said that those three were blend uniformity failures, that wouldn't technically be correct; would it?

MR. MILLER: Object to form.

A. I want to make sure I -- may I have the question again, please?

Q. If somebody colloquially --

A. Okay.

Q. -- said those three are blend uniformity failures, that would not be technically correct?

MR. MILLER: Object to form.

Q. Am I right?

A. If you do the repeat test and they pass, no.

To be clear, there is FDA guidance on doing just that.

Q. We have only got a couple of minutes left on the tape, so we might as well take our break now.

THE VIDEOGRAPHER: Please stand by.

MR. MORIARTY: And we're off the record?

THE VIDEOGRAPHER: We are going off the record. The time is 11:02 a.m. This is the end of Tape Number 2.

(A recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 11:12 a.m. This is the beginning of Tape Number 3.

Q. Now, Dr. Somma, I touched very briefly earlier on the concept of batch yields; correct?

A. Yes, sir.

Q. And would you agree with me that if you consistently put too much active pharmaceutical ingredient into your solid oral dose, it could be detected at a number of different places; and one might be the inventory of your active pharmaceutical ingredient; correct?

A. Absolutely.

Q. Another could be at the blend uniformity stage. Is that correct?

A. That is correct, assuming the sampling and the testing is good, sure, yeah.

Q. Another could be your finished product stage?

A. Absolutely. And at that stage it becomes

compounded by the blend part and the compression part.

Q. Okay.

A. You can still find it. I agree with you.

Q. Sure. And if there was testing done by an outside entity for whatever reason, it could theoretically be picked up there; correct?

A. Theoretically, yes.

Q. All right. And if you were consistently putting too much adverse -- I mean active pharmaceutical ingredient into your product and it had the potential to harm patients, another potential place to see a problem would be an increase in your adverse event reporting. Is that true?

A. I would -- I would agree with that, yes.

Q. Okay.

A. It's a true statement.

Q. Now, I think you told me earlier you are not an expert in pharmacovigilance; right?

A. No, sir.

Q. Have you done any study in this case of Actavis' pharmacovigilance or their adverse effect reporting rates?

A. No, sir.

Q. And a pharmacovigilance expert for the plaintiffs, a Dr. Frank, was deposed yesterday, and I

know you don't know anything about what she said, but would you generally defer to an expert like her in pharmacovigilance on the subject -- on that subject in this case?

MR. MILLER: Object to form.

A. Absolutely, Matt.

Q. Okay. And to stick with this batch yield concept, if a company consistently made double thick tablets, there would be a number of places you might catch that as well; correct?

MR. MILLER: Object to form.

A. You would expect to catch that at certain places. I would have to agree with that.

Q. For example, even if we just worked backwards, if you used the appropriate amount of ingredients from the start but made double-thick tablets, you wouldn't have as many tablets; right?

A. If you made all of them double thick. Yeah.

Q. Right.

A. Occasionally one, Matt; really, realistically, you couldn't detect it.

Q. I understand that. But I'm saying if you made lots of them, you wouldn't have as many tablets; right?

A. You're correct.

Q. Okay.
A. You're correct.
Q. Hence, you wouldn't have as many bottles; right? To fill at the packaging station?
A. You're correct, yeah.
Q. And those sort of things are looked at by companies as further quality checks to see if the processes are following their validated methods; right?
A. Absolutely correct, Matt. The problem would have to be pretty extreme, though, to pick it up in that manner.
Q. Okay. Well, it sounded to me like your pharmaceutical consulting engagement where they had extra-thick tablets was an instance where there were just a few among either a batch or several batches; correct?
A. That's right.
Q. Was it one batch?
A. I looked at the batch that the sample was returned from.
Q. Did they only find them in one batch?
A. I don't know what -- to be perfectly honest, I don't know what else they found. I did not find any indication of them in the batches, before and after, I

looked at; no, sir. There were no complaints, no returns, no nothing.

Q. Okay. And theoretically in order to actually harm patients, for enough of these to get out into a lot of bottles and out through the entire distribution system over years and years, you would have to make a lot of extra-thick tablets; wouldn't you?

MR. MILLER: Object to form.

A. I guess, but it only takes one bad tablet to create a harm, and that's why this complaint was dealt with like this particular company that I worked for, yeah.

Q. Well, I think we established that you are not a pharmacokineticist, a pharmacologist; you are certainly not a physician; correct?

A. Definitely not.

Q. You don't know whether one Digitek tablet that was extra thick would harm a patient or not; do you?

A. No, sir. And the fact is that we don't even know what the composition of that thick tablet was.

Q. There could be an extra-thick tablet that's just bigger because it wasn't compacted appropriately; right?

A. So that would be -- that is certainly within

the realm of possibility, yes, sir.

Q. All right. So if you subjected that tablet to a hardness testing, it might shatter like an egg; correct?

A. If it would survive packaging, yes, sir. Which is what friability and hardness is supposed to prevent, right.

Q. Do you know how many people in the United States were described digoxin between 2006 and 2008?

A. No, sir.

Q. Do you know how many prescriptions were written for digoxin between 2006 and 2008?

A. No.

Q. Do you know how many people were taking Digitek between 2006 and 2008?

A. No, sir.

Q. Do you know how many prescriptions were written for Digitek between 2006 and 2008?

A. No, sir.

Q. Now, do you know the theoretical batch size of a Digitek 125 microgram batch?

A. 4.8 million.

Q. And the theoretical size for a 250 microgram is what?

A. I think it was 4.2 million, but that's by

memory.

Q. Okay.

A. I don't know if that's correct.

Q. So if you do the math of 152 recalled batches, you're up in the 688.2 million range for tablets; are you not?

A. Yes.

Q. Depending on how many batches of each?

A. How many tablets are made; yes, sir.

Q. All right.

A. It's 152 times 4.8, right, okay.

Q. Do you know how many were recalled in either of the two dose strengths?

A. No, sir.

Q. Of the number of batches that were actually recalled from the market, do you know how many of those tablets never made it to consumers?

A. No, sir.

MR. MILLER: Object to form.

A. No, sir.

Q. You know that there was a recall; correct?

A. From what you told me, 152 batches; yes, sir.

Q. Well -- and tablets were supposed to be sent from pharmacies and hospitals that still had them back to a recall center; correct?

A. Right, I was aware of that, yes, sir.
Q. Do you know how many tablets were returned?
A. No, sir.
Q. So I want you to assume that -- and I just keep referring to the recall batches more for convenience, but if you want to go back to 2004, we can.

Do you know whether each batch of Digitek that was made between 2004 and 2008 was subjected to quality control, USP method, finished product testing?

MR. MILLER: Object to form.

A. Based on what I've seen, every batch was tested, yes, sir.
Q. Right. And you don't know of any that failed that testing; do you?
A. To my knowledge, no, sir.
Q. And you don't have any question or criticism of the sample size or the method they used; correct?
A. No, sir.
Q. Or the integrity of the data?
A. No, sir.
Q. So what I want to ask you is about testing that was done by other people.
A. Okay.
Q. Do you know what the batch certification

program was?

A. That they -- as I recall, based on what I've read, it was samples had to be provided to FDA for them to confirm at their laboratory that these met requirements.

Q. Right. Was that going on when you worked at Novartis in the '90s?

A. I wouldn't know that, sir. I wouldn't.

Q. All right. I want to hand you what actually should be in the stack, Exhibit 4?

A. It was right on the top, yes.

Q. It should be near the top. I had them in order.

A. It was right here. I remember looking at it.

Q. Okay. Do you have Exhibit 4?

A. That's it.

Q. That's a letter to Amide at the time from FDA, is it not?

A. Yes, sir.

Q. Certifying nine batches of Digitek; correct?

A. Uh-huh, yes, sir.

Q. Presumably all tested by FDA itself. Is that right?

A. That's how I understand that, yes. And they all met requirements.

Q. And Exhibit 5 is in that stack?
A. Yes, it is.
Q. Is that a July, 1995 letter from FDA to Amide exempting them from the batch certification process?
A. Yes, it is.
Q. Presumably at that point FDA was confident that Amide was making the product within its specifications consistently; correct?
MR. MILLER: Object to form.
A. As far as I read this, yes. Everything was as they anticipated it would be.
Q. Do you know what Quantic Regulatory Services is?
A. It's a consulting firm as far as I know, sir.
Q. Do you know anything about them?
A. Other than that their specialty is consent decree remediation. That's the only thing I know about them.
Q. Do you know if they are reliable?
A. I couldn't say that one way or the other, sir.
Q. Are they well-regarded by FDA?
MR. MILLER: Object to form.
A. I think that they are on the list of people that FDA says to use in consent decree remediation. I

would think that says it right there.

Q. Okay. And I'd like you to look in the exhibit stack for Exhibit 22 and 23. Do you have 22 and 23?

A. Yes, I do, Matt.

Q. All right. I'm going to have to do this from memory because I can't find my copies of those two exhibits, but 22 should be a warning letter from the FDA. Is that right?

A. That's what it says, yes, sir.

Q. And -- oh, I found it.

At the back, second-to-last page, last paragraph. They say, "We feel that to provide such assurance, your firm should promptly initiate an audit program by a third party having appropriate cGMP experience to provide assurance that all marketed lots of drug products that remain within expiration have their appropriate identity, strength, quality and purity."

Did I read that correctly?

A. Yes, you did.

Q. This is an invitation by the FDA in a warning letter to hire a consultant; correct?

MR. MILLER: Object to form.

A. As I understand it, yes, sir.

MR. MORIARTY: All right. What's wrong with the form of that question?

MR. MILLER: I object to the term "invitation."

MR. MORIARTY: Okay.

Q. Let's get back to the basic definition of a warning letter. A warning letter is not a "you must" in the eyes of the FDA; correct?

A. Yes, Matt. I recall we discussed it and it was informal.

Q. Right. And it is urging voluntary compliance with the regs; is it not?

A. Yes, sir. It's -- you don't ignore them, Matt. Let's put it that way.

Q. I understand from a company perspective you wouldn't want to ignore them, but --

A. Gun to your head?

Q. "Invitation" isn't an inappropriate word when -- in your mind, when I asked you that question; is it?

A. To be honest, I was thinking what -- what they were asking here/ and to me, yeah, well, that means you better get yourself a consultant, period, end of story.

Q. Okay.

A. You know.
Q. All right.
A. What you call it, whatever.
Q. All right. Let's go to Exhibit 23.
Have you ever seen Exhibit 23 before?
A. No, sir.
Q. All right. Exhibit 23, do you know --
MR. MORIARTY: Let me withdraw and start over.
Q. Do you know that in response to Exhibit 22, Actavis went out and hired Quantic Regulatory Services to do the remediation of that warning letter?
A. I did not know that as fact.
Q. Okay. Well, I want you to assume that my client hired Quantic, and that Quantic looked at batch -- batch records. Okay?
Now, if you look, if you flip through here you will see that obviously pages are redacted with the names of other products, but at Bates Page 1867202, 1867202, you see that there are Digitek batches there?
A. Yes, sir.
Q. And then if you flip further back to Bates Page 1867214, and spilling over onto the next page, there are a number of other Digitek batches; correct?
A. Yes, sir.

Q. Do you know what kind of batch record review they performed?
A. No, sir.
Q. You don't know anything about the protocol they used to analyze the batch records?
A. No, Matt, I don't know.
Q. All right. Do you know how many of these batches wound up being in the recall --
A. No, sir.
Q. -- batches?
A. No, sir.
Q. Let's go back to the cover page.
A. This?
Q. Yes. It says, "On December 21st, 2007, Quantic provided Actavis with a statement indicating the audit was complete and the manufacturing and laboratory records have reliably confirmed the identity, strength, quality and purity of the marketed products."

Do you see that statement?
A. Yes, sir.
Q. If that is in fact was Quantic concluded, do you have any reason to disagree with them?
A. No, sir, I don't, based on what I know and what I've read.

Q. Do you know whether or not FDA accepted Quantic's analysis and this letter from my client in remediation of the warning letter, or whether they rejected it?

MR. MILLER: Object to form.

A. No, sir.

Q. Okay. I'm going to go through a number of exhibits in this stack, so --

A. Okay.

Q. Let's go to Exhibit 24. Do you have 24?

A. Yes, Matt, I do.

Q. Have you ever seen it before?

A. No, sir.

Q. I'm sorry?

A. No, sir.

Q. You didn't see it yesterday when you met with Pete and Meghan?

A. No, sir.

Q. Do you know what a 484 sample is?

A. Yes, sir. It's a sample collection, sir.

Q. Did FDA ever come to Novartis and collect 484 samples of drug products?

A. Yes, sir, but I was not involved. I just knew of it, sir.

Q. So if you go to the first page of Exhibit 24,

and you and I might have to get a lot closer because I can run you through these quickly.

But if you look here --

A. Okay.

Q. -- this is Sample 377410.

A. Yes, sir.

Q. Do you see that?

A. Yes, sir.

Q. Down to the left, it was collected February 9th of 2007. Do you see that?

A. Oh, yeah, great. Right here. February 26.

Q. I'm pointing to these over here if you want some guidance. I've highlighted them.

A. I'm sorry. Okay. Yeah. February 9th, right.

Q. And in the middle where I'm pointing with my pinky, it has the manufacturer's batch number as 70078A1. Do you see that?

A. Yes, sir.

Q. Down here it describes the sample, 200 count bottles of digoxin, .125. Is that correct?

A. Right.

Q. And if you want to flip through all this you can, but I will represent to you that they subjected this to USP method, assay, content uniformity --

A. Right.
Q. -- testing, and all the backup data from the chromatographs is attached to this. Okay?
Do you have any reason to disagree with any of what I just said?
A. Absolutely not. Just for clarity, Matt, these are -- this was done by the FDA laboratory or somebody; correct?
Q. They tested it; right?
A. Yeah, fine.
Q. To your knowledge, FDA does have labs that do this; correct?
A. Yes, sir, they do, forensic laboratories.
Q. And if you go to this page, if you can see this page, in the upper right-hand corner where it says, "District or lab," it says, "DEN/DO."
They have a lab in Denver; don't they?
A. Uh-huh.
Q. Yes?
A. Yes.
Q. I'm sorry to say that, but Mark needs to hear it.
A. I understand, sir. It's a bad habit of mine.
(A discussion is held off the record.)

Q. And to your knowledge, did this sample pass all of the tests to which the FDA subjected it?

MR. MILLER: Object to form.

A. Well, I haven't read through, but my -- based on what's here, meets, yes.

Q. All right.

A. There is no reason to think that it doesn't.

Q. Let's go to Exhibit --

Well, do you have any -- have you seen any evidence to indicate that this batch did not meet all of its specifications?

A. Absolutely not.

Q. Let's go to Exhibit 25. Is this another 484 sample report?

A. It's similar format of sample collection, yes.

Q. Up here it says Sample 44881; does it not?

A. Yes, sir.

Q. And down here if you flip through this, you can see that they collected -- if you go to the second page, on December 3rd, 2007 they collected from a Wal-Mart Pharmacy warehouse 200 count bottles of Digitek; right?

A. Uh-huh, yes, sir.

Q. Batch 70298A1; right?

A. 70298A1, yes, sir.
Q. And on the first page, if you flip back, they have a Lab Conclusion near the bottom. It says, "The product meets specifications for identification, dissolution and content uniformity." Is that right?
A. Yes, it does say that.
Q. Now, have you seen any evidence in any documents that you've reviewed that shows that any of the tablets from this batch were out of specification?
A. No, sir. But where does it say the product meets specifications on this one? Did I miss that? I'm sorry. I don't --
Q. Are you talking about Exhibit 24?
A. I'm sorry. 24, yeah.
Q. Do you want to dig through it?
A. Well, I just -- it's not a headline like this one is. I can see that.
Q. If you want to review it, go ahead. If you find that that batch when tested by FDA was out of specs --
A. No.
Q. -- let me know.
A. I'm agreeing it's in spec. I'm just wondering how come they don't put it in the front on this one. Go ahead.

Q. Let's go to Exhibit 26. Look at the second page of that one. I don't know why it got marked that way.

A. Yes, Matt.

Q. Do you have it?

A. Yes, sir.

Q. It's Sample Number -- the shading is so bad. Oh, Sample 448892.

A. Yes, sir. And that meets requirements.

Q. And it was collected in December of 2007 from a Wal-Mart Pharmacy?

A. Yes it was.

Q. And it's Batch 70664A. Is that right?

A. Yes, it is.

Q. And on the first page of Exhibit 26, "The product meets specifications for identification, dissolution and content uniformity."

Do you see that?

A. Yes, sir.

Q. Have you seen any evidence the tablets from this batch were out of specification?

A. Not in anything I reviewed.

Q. Let's go to Exhibit 27.

A. Okay.

Q. Before I ask you about Exhibit 27, when you

worked for Novartis, were you ever made aware after the fact that FDA had done a 484 sample and passed your company's products?

A. Not customarily, Matt, no.

Q. Okay. As a consultant when you are doing an investigation about the integrity of the product in the field --

A. Yeah.

Q. -- would you inquire about 484 samples that may have been tested by FDA itself?

A. In -- when we would interview the client, just to get a sense of what the level of involvement was, yes, sir.

Q. Okay. Is it interesting and helpful information to know?

A. It's another set of eyes looking at the information in an independent laboratory; always good to have as a backup validation, Matt.

Q. It's -- is it more than a set of eyes? It's -- it's scientific testing of tablets; right?

A. It's scientific testing of tablets. I apologize for denigrating it to "eyes," but that's what I mean; it's another set of expertise looking at it. Independent, if it's regulatory or somebody else.

Q. Okay. And FDA, when they take the samples,

can take as many as they want; correct?
A. That I don't know, sir.
Q. Can they test as many as they want?
A. Again, I'm ignorant of that fact. I don't know.
Q. Do you assume that FDA chooses a sample size that they think is statistically significant?
A. Based on uniform --
MR. MILLER: Object to form.
A. I guess that's a reasonable estimate based on batch size. I would also think that FDA could take whatever they want.
Q. Okay. So let's go to Exhibit 27.
A. Okay.
Q. This is FDA Sample 453913; correct?
A. 453913?
Q. Yes?
A. Yes, sir, it is.
Q. Okay. Collected February 15, 2008; right?
It's up here in the left-hand corner.
A. Sorry. Yes, sir.
Q. Batch 70737A; correct?
A. Yes, sir, yes, sir.
Q. And it was collected from a warehouse -- I'm not sure where. But if you go to the third page,

there's a Lab Conclusion; right?

A. Yes.

Q. Did it pass all the tests to which FDA subjected it?

A. It says that it meets USP requirements for identification, CU and dissolution; yes, sir.

Q. Let's go to Exhibit 28.

Now, I know before today you hadn't seen these exhibits, but did you know generally that FDA had repeatedly tested Digitek in the field?

A. No, sir.

Q. Do you think for your analysis in this case, it would have been important for you to know that?

A. No, sir.

Q. You don't think statistically significant testing by FDA itself corroborating my client's QC results is significant information?

MR. MILLER: Object to form.

A. I would say based on balance, if a firm comes to me and offers a batch record which they say is approved, I don't need any outside corroboration. To answer your question specifically, that would have been nice, but I take it at face value what the client has done.

Q. All right. So Exhibit 28 is FDA Sample

454866; is it not?

A. 454866, yes.

Q. And it's another sample of a Digitek batch; correct?

A. Yes, sir.

Q. And if you look way at the back, the third from the last page, you will see it was collected February 15th, 2008. Upper left corner.

A. Okay, yes, sir.

Q. And it's Batch 70811A; correct?

A. Yes, sir.

Q. It was collected from a McKesson warehouse. Is that right?

A. In Duluth, yes, sir.

Q. And let's go all the way to the front.

Is there a Lab Conclusion? First page.

A. Same as before, Matt: Meets requirements for dissolution and content uniformity.

Q. Let's go to Exhibit 29, please. Do you have it?

A. Yes, sir.

Q. Do you see that it is FDA Sample 462746?

A. Correct; yes, sir.

Q. And if you go to the third page, you can see that it's another Digitek sample; correct? Very top in

the center?
A. Right.
Q. And just below that, they received this sample in April of 2008; right?
A. 4/3/08; yes, sir.
Q. And if you go back to the second page -- I'm sorry. Well, let's just go to the Lab Conclusion.
A. Uh-huh.
Q. Second page. Did it pass all the tests to which FDA subjected it?
A. Lab Conclusion, it meets specifications; yes, sir.
Q. Was this in a blister pack?
A. I'll have to read it, Matt.
Q. Third page, halfway down in the big "Summary of Analysis" box. Do you see that?
A. Yeah, I guess I do.
Q. All right. And I want you to assume that this is Actavis batch 70300A. Okay?
A. Yes, sir.
Q. Have you seen any information to indicate that that Actavis batch had out-of-specification tablets?
A. No, I did not. Matt, and to confirm your first question, it is in a blister, based on this

description.

Q. And I didn't ask you that last question on several of these batch exhibits; but have you seen any evidence to indicate that any of the batches I've asked you about with these FDA samples were out of specification?

A. Nothing that would -- nothing that would bring me to that conclusion.

Q. All right. So let's go to Exhibit 30.

Is it FDA Sample 462753?

A. Yes, it is.

Q. Was it collected in March of 2008?

A. March 21st, 2008; yes, sir.

Q. From a Wal-Mart in California?

A. Right; yes, sir.

Q. And the batch says, "8A 332."

Do you see that?

A. Yes, sir.

Q. And that is a UDL batch number, which corresponds to --

A. UDL is?

Q. That's Batch 70834A.

A. I'm sorry. What is UDL?

Q. You don't know what UDL is?

A. No.

Q. Okay. We'll get to that.
A. Okay.
Q. This is a Digitek sample, is it not? Exhibit 30? It's right --
A. Digitek, right. Got it.
Q. And I'd like you to go to the third page of the exhibit.
A. Got it.
Q. Is there a Lab Conclusion?
A. There sure is.
Q. What's the conclusion?
A. That they meet specifications for identity -- identification, dissolution and content uniformity.
Q. Do you have any evidence from anything in front of you to indicate that any tablets from this batch were out of specification?
A. No.
Q. Let's go to Exhibit 31, please.
And I'll represent to you when you get back to 2002, their records get a lot thinner.
Is this another 484 sample?
A. It looks to be.
Q. From March of 2002?
A. Yes.
Q. And the -- for Digitek?

A. Product description; yes, it is.
Q. Is there a Lab Conclusion in the center of the page?
A. It meets USP's uniformity of dosage unit specifications, but it says nothing about dissolution.
Q. Well, why don't you go to the very last test on the page?
A. There it is.
Q. What it does it say about dissolution?
A. There it is. Meets dissolution on -- I didn't read that far.
Q. You don't have any evidence that any of these tablets from that batch were out of spec; do you?
A. No, sir.
Q. Are you aware that at least this testing exceeds the recall parameter dates?
A. Well, this is -- is that based on this date, Matt, '02?
Q. Well, do you know when the recalled batches were first manufactured?
A. I don't know that date, to be honest with you.
Q. All right. Let's go to Exhibit 32, please.
Is this another FDA Form 484 sample?
A. Yes, sir.

Q. Sample 157504?
A. Yes, sir.
Q. For Digitek?
A. Yes, sir.
Q. Center of the page, what was the Lab Conclusion?
A. USP uniformity of dosage units. It looks like it meets. It also meets USP requirements for dissolution.
Q. All right. Exhibit 33, please.
Is this another FDA 484 Digitek sample?
A. Yes, it is.
Q. Sample 178890?
A. Correct.
Q. Now, in the Lab section, does it say anything other than "in compliance"?
Do you see where I'm talking about?
A. Yeah, yeah, right in the middle there, "in compliance." I don't see any other comment. It says that in two places.
Q. Okay. Would you assume that that's -- that it passed both content uniformity and dissolution?
A. I would, simply because this is the same laboratory that did the prior, and it uses the "in compliance," and it does note that it meets.

Q. Okay.
A. Even though it's absent here.
Q. All right.
A. Okay?
Q. So look at Exhibit 34, please.
Is that another FDA Form 484 sample report?
A. 178891, yes, it is.
Q. And -- for Digitek?
A. Correct.
Q. And halfway down the page, does it indicate in two different places that the product was in compliance?
A. That's correct.
Q. Now, have you read anything in any of the material that you have seen to indicate to you who UDL was?
A. I have to admit that I cannot remember UDL.
Q. All right.
A. To be perfectly honest, I think I've asked the question. I just do not remember the answer.
Q. From all the material that you reviewed from Actavis, did Actavis always package its product in bottles?
A. Everything I looked at went into bottles, yes, sir.

Q. All right. You know the manufacturing of -- and packaging of pharmaceuticals, so at some point what would -- what assumption would you make about how Digitek got into blister packs?

A. They would have had to have gone with a third party contractor to do that, if they didn't have the capability themselves.

Q. Okay. I want you to assume that that third-party contractor is UDL. Okay?

A. I got it.

Q. Did Novartis make any product in blister packs?

A. We were a European-based company, Matt. Every product was offered in blisters.

Q. Okay. What did Novartis do --

(A discussion is held off the record.)

A. Every product we made was made in blisters. We distributed in Europe.

Q. What did Novartis do to make sure that tablets would fit into blisters?

MR. MILLER: Object to form.

A. We would -- we would design the blisters such that it would fit within a normal range. What that means, Matt, was: We didn't custom-make blister tools. We made sure that our tablets were made to

engage, that would accommodate blister tooling downstream.

Q. Well, what would happen if by accident, Novartis made some double-thick tablets? Would they fit into your blisters?

A. This would be more of an opinion, I think, for me. I would think based on what I've seen in the past, some would, some wouldn't. I'm not trying to be evasive here.

Q. In pharmaceutical packaging, you want the blister to be relatively tight to the tablet; don't you?

And I'll give you two reasons why. Do you agree with me it should be tight to the tablet, relatively speaking?

MS. CARTER: Object to form.

A. In general I agree with you, Matt. I'm trying to think -- from my experience, I'm trying to picture some of it.

Q. Well, you don't want a lot of space --

A. No.

Q. -- because the tablet could bounce around and break; right?

A. We both agree to that. It's not going to rattle like a kid's toy. Okay?

Q. And if you use too much packaging, you are kind of wasting resources; aren't you?
A. Precisely.
Q. All right.
A. We are in agreement there.
Q. All right. Do you know anything about what UDL did to check tablet thickness of Digitek before it put it in blister packs?
A. No, sir.
Q. Okay. Could you look in the stack for Exhibit 35? It's right there.
A. Sure. It's right here.
Q. All right. Look at the first page. First of all, is this on Celsis Analytical Services letterhead?
A. Yes, Matt, that's what it says.
Q. Do you know who Celsis Analytical Service is?
A. I would just assume is a third-party analytical laboratory. That's all I can say. I have not heard of them myself.
Q. In the center, do you see the names of the three samples?
A. Digitek, yes, sir.
Q. Three different batches?
A. Yes, sir.
Q. And at the very bottom, the date is January

29th, 2007?

A. Yes, sir.

Q. I want you to flip back to Bates Page UDL011685. I skipped a few zeros. It's not very far back.

A. Yeah. Got it.

Q. Do you see that? Does it appear to you that this is the certificate of analysis for this product by Actavis?

A. That's what it says; yes, sir.

Q. All right. And then if you flip back to -- further, do you see that Celsis did some independent testing of this?

A. Yes, sir.

MR. MILLER: Now, when you say flip back a little bit further, do you have a specific page?

MR. MORIARTY: There's lots of pages, Pete.

Q. I would start at UDL11687.

A. Yes, sir.

Q. And go back. All right?

Does it appear to you from 11687 that this product passed the tests to which Celsis submitted it?

I'm sorry. That was a bad question.

From Page 11687, does it appear to you that -- that the product passed the tests to which

Celsis subjected it?

A. Based on these numbers, yes, Matt, it did --

Q. All right.

A. -- pass.

Q. Now let's go back to 11717.

A. Okay.

Q. Is that the certificate of analysis for a different batch than we just discussed?

A. Sorry, Matt. I went to the wrong page. Can we have that page number again, Matt?

MR. MILLER: 11717.

(A discussion is held off the record.)

Q. 11685. It's Batch 61100.

The one I'm now asking you about at 11717 is Batch 61097. Okay?

A. I got you.

Q. So we're up to a different batch; correct?

A. I got it now, yes, sir.

Q. All right. And if you go two pages more to 11719, does it appear to you that the product passed the tests to which Celsis subjected it?

A. Yes, it does.

Q. Let's go all the way back to 11746.

A. Okay.

Q. Is this the Actavis certificate of analysis

for yet a third batch, 60992A?

A. Yes, it is, Matt.

Q. And if you go two more pages, does it appear that the product passed all the tests to which Celsis subjected it?

A. Based on the information here, it met every requirement.

Q. Have you seen any evidence in any material that you reviewed to indicate that any of these three batches had out-of-specification testing by anyone?

A. These three batches, no Matt. I do not.

Q. Let's go to Exhibit 69. Is 69 in the stack?

(A discussion is held off the record.)

A. 69, got it.

Q. All right. Is this a UDL Lab document?

A. Yes, it is.

Q. And if you look a little bit way down, this is regarding Actavis Batch 80111A; correct?

A. Yes, it is.

Q. And if you go to the -- about the middle. It's UDL7655.

A. Yes, sir.

Q. Did they measure Digitek tablets in two dimensions?

A. Yes, they did.

Q. Were any of them out of spec?
A. I don't recall the spec off the top. Is it written here? I have to go back and look.
Q. It's at the very bottom.
A. There it is, I see it.
Q. Actually, that's not correct. That may be the range they found.
A. But just for our both's sake, I'll look at the batch record. Okay?
Q. Sure.
A. Is that okay?
Q. Oh, it's fine. Oh, yeah. If you think it's in there.
A. It's in the compression sheets.
(A discussion is held off the record.)
Q. Okay. The thickness range for 250 micrograms is 2.7 to 3.7 millimeters.
A. 2.7 to 3.7? So based on that, these fall well within mid range. Okay?
Q. All right.
A. And just for clarity, Matt, what I was -- this was -- I just put down a bunch of numbers because I have trouble remembering specifications. I just wrote them down on here. Okay? It's no big --
Q. Sure.

A. And I didn't have that either, just to be clear.

Q. Okay. Let's go to Exhibit 70, which I did not mark the other day. Here it is.

Is this another UDL Laboratories sheet?

A. Yes, it is.

Q. Regarding Digitek Batch 71034A?

A. Yes, it is.

Q. And if you go to a similar spot in this document, it's the last one, do you see the product dimension records?

A. Right.

Q. And this is for another 250 microgram batch?

A. I know all fall well within the mid range.

Q. All within spec?

A. All within spec, yes.

Q. Let's go to Exhibit 71. Here you go.

A. Thanks.

Q. And is this a UDL Laboratories sheet?

A. Yes, it is.

Q. Regarding Actavis Batch 71004A?

A. Yes, it is.

Q. And this is a 125-microgram lot; correct?

A. Correct.

Q. And if you assume that the thickness specs

for that product are two to three millimeters, did all these pass?

A. You pulled that right off the batch record, Matt?

Q. I guess you'll just have to trust me.

A. I'm good.

Q. It's in the ANDA.

A. And it's also right here, too.

Q. So --

A. The answer is -- the exhibit here shows that this result of thickness falls within the mid range of their specification thickness.

Q. Okay. Let's go to Exhibit 72.

Is this another UDL document?

A. Yes, it is.

Q. Regarding Batch 70175A?

A. Right.

Q. Please go to the same place. This is a 250 microgram batch.

A. Got it.

Q. Did all the 20 tablets that they measured meet the specs?

A. The specs being 2.7 millimeters to 3.7 millimeters; this batch falls right in the middle of the range.

Q. Okay. Let's go to Exhibit 73.

Have you ever seen this document before?

A. No, sir.

Q. Had you ever seen any of those UDL documents I just showed you?

A. No, Matt, I did not.

Q. Does this say, "UDL Internal Investigation Record"?

A. It sure does; yes, sir.

Q. Do you see that this was in -- let me find the date. On the last page, May of 2008.

A. Right.

Q. And can you tell from the first page of the -- this, that this investigation was done because there was a recall going on?

A. Just give me a minute, Matt.

Okay. "Class 1 drug recall nationwide," got it. "Is being recalled."

(A discussion is held off the record.)

A. Product recall is obvious based on this statement, yes, sir.

Q. And UDL investigated -- at the third page, you can see a complaint history with this product. Do you see that?

A. Just give me a sec.

Q. Well, I'll tell you what.

MR. MORIARTY: Let me withdraw that question.

Q. Let's go to the second page. Do you see that under "Investigation Summary," they have a section on receiving inspection records?

A. Yes.

MR. MILLER: Wait a minute. I'm not with you.

MR. MORIARTY: Second page, top.

MR. MILLER: Okay. Got it.

Q. And then there's a section called "Batch Record Documentation"? Do you see that?

A. Yes, I see it, Matt.

Q. Is there a section called "Examination of Retained Samples"?

A. Right. The copy starts to get a little fuzzy down there, but I can see that, yes.

Q. And then on the next page at the top, "Complaint History"? Do you see that?

A. Right.

Q. Now, if you were going to do -- I'm sorry. I'm not --

On the last page, it says "Stability records history." Do you see that?

A. Yes, I do.

Q. If you were going to do an investigation, are

these the kind of things that you would look at?
A. If I was aware that this was one of the put-ups that I had that was problematic. I think this would be a substantive piece of information. It would certainly give me a sense to -- of the tablet gauge.
Q. Okay.
A. Because certainly downstream packaging, especially in something as -- as punitive as a blister, it's important to know.
Q. Okay. And go to the last page. Do you see they have a "Conclusion"? Just above the signature?
A. Right.
Q. Do you see that?
A. "UDL is continuing a voluntary --"
Q. No, no. Above that.
A. I'm sorry.
Q. It says, "Conclusion." Do you see that?
A. Yes.
Q. It says, "Records reviewed, retained sample examination and complaint history for products and lots in question demonstrate no evidence of unusual events that could be related to the packaging of double the thickness tablets in unit dose blisters."
Do you see that?
A. I see it; yes, sir.

Q. Okay. Let's go to number -- Exhibit 83.

Good luck with this one. I want you to take a minute to look through that.

First of all, have you ever seen it before?

A. No, sir.

Q. All right. I'm going to walk you through this.

A. All right.

Q. Do you see that this is on UDL Labs letterhead?

A. Yes.

Q. From your own knowledge of the pharmaceutical industry, would a repackager have an obligation to do dissolution testing in order to assess whether their repackaging of the product had any effect on shelf life or stability?

A. That would depend on the product. Customarily you want to make sure that the environment in which you package the product doesn't affect it. In other words, it going to be there in bulk.

Q. Okay.

A. So in that case, you'd want to do everything necessary to assure that. Okay?

Q. So let's go back to -- let's go back to the first page, I guess. Is this a transmittal form?

A. Yes, that's what it says.
Q. And essentially what it is telling us is that on January 29th, 2007, UDL shipped Celsis Laboratories three Digitek samples. Is that right?
A. Yes, it is.
Q. And if we flip through the remaining pages, you see that on various other dates, UDL sent RD Laboratories in Missouri various other Digitek samples; is that right?
A. Right, yes. It looks like these are stability samples.
Q. Okay. So let's go back to the actual Results sections.
Now, I can tell you, Dr. Somma, that I have read this document and I think there are 33 batches of Digitek over the years that UDL sent to either Celsis or RD. Okay? You are welcome to count them if you'd like, but I just want to go through a few of them.
A. Okay.
MR. MILLER: What page are you on?
Q. Not all 33 of them.
MR. MORIARTY: I am on UDL11369.
MR. MILLER: Okay.
Q. Do you see that this is a stability test result?

A. Yeah, yes, sir.
Q. For, on the right-hand side in the corner, Actavis Lot 70834A? Upper right-hand corner.
A. The other right. 703 -- 70834A, yes, sir.
Q. And the initial testing in October of 2007 showed an assay of 97.3 percent; correct?
A. Yeah, yes, sir.
Q. Are you familiar with this kind of stability test reporting?
A. Yes, sir.
Q. Would you assume that the initial October of 2007 was what Actavis tested at the time of finished product testing?
A. That -- is this a confirmation -- is this aligned with their results?
Q. I don't know. I'm just asking what you know about this. If you don't know, I don't want you to guess.
A. That I couldn't answer, then.
Q. Okay.
A. If they are both working with the same spec and the same method and it's been transferred, it should be right within -- right within experimental error.
Q. Okay. So let's go to the next page, UDL

11370, and in the upper right, this is Batch 70386A.

A. Right.

Q. Correct?

A. Uh-huh.

Q. And on this page in May of '07, the assay result was 97.1. Is that correct?

A. 97.1, yes, sir.

Q. Percent?

A. Percent. Okay.

Q. And if you look at the bottom on the left, it says the manufacturing date of May of '07.

Do you see that?

A. Uh-huh.

Q. That's yes?

A. Yes, sir. And I see --

Q. And a manufacturer's assay of 97.1 percent; correct?

A. Right.

Q. Is it reasonable to conclude, therefore, that this top part where the initial -- it lists the initial assay, is the original Actavis assay when it made the batch?

MR. MILLER: Object to form.

A. In my experience, what happens is your Time Zero is usually not repeated. That would be -- it

could have been data that was there, and they just used that as Time Zero.

Q. Okay.

A. Okay? So Matt, that would be why they're the same.

Q. Right.

A. But, again, I wouldn't know that for a fact. That's my experience.

Q. When UDL gets the certificate of analysis from Actavis, it has the assay results with it?

A. Right. So that would be Time Zero.

Q. Okay. So the next section says, "Shelf life testing, three months, assay result 97.2."

Do you see that?

A. Yes, sir.

Q. And that's within the specifications. Is that right?

A. It sure is, yes, sir.

Q. Now, if we flip back through every one of these pages, is the format essentially the same, where the Actavis lot is in the upper right-hand corner?

A. Yes.

Q. And the assay results to which either Celsis or RD tested the Digitek are contained in these grid charts. Is that right?

A. Yes, sir.
Q. All right. I would like you to flip through all those pages and tell me if there was ever a stability failure of Digitek when tested at the request of UDL?
MS. CARTER: Object to the form.
A. On several occasions, Matt, these are dissolution results at the S2 level. My experience, those would precipitate an investigation. But did they fail? No.
I'm looking at specifically Page 11373. It notes it as an S2. That just means that you increase the sampling.
Q. Okay.
A. But, again, not knowing that part of it, that usually precipitates an evaluation. It is not per se a failure. Okay?
MR. MILLER: If we're going to leave this document, it might be a good time for lunch.
MR. MORIARTY: Let me finish up.
A. When I'm done --
MR. MORIARTY: Let me finish up my section. I have another exhibit. And maybe one or two more questions.
MR. MILLER: Okay.

(A discussion is held off the record.)

Q. Do you see any stability failures?

A. Other than those comments I made about S2, there are no stability failures in here.

Q. And stability testing is doing assay of the product over time; is it not?

A. Yes, it is.

Q. Okay. I want to hand you what I had marked as Exhibit 84. This is another UDL document.

Have you ever seen this before?

A. No, sir.

Q. Had you ever seen all that stability testing before?

A. This? I never looked at that.

Q. All right. This is a memo, is it not, dated May 5th, 2008?

A. That's correct.

Q. And if you go to the second paragraph, third line down, it says, "UDL tests the product for potential and dissolution. In reviewing the data for both strengths of Digitek, the potency showed no apparent trending."

Let me stop there. Have you seen anything in the documents that I have given you so far to indicate there was any adverse trending to the Digitek data?

MR. MILLER: Object to form.

A. To answer it accurately, Matt, I would have to look at all of that information together. My sense is: Based on those numbers I looked at, they were all within the mid to high 90s.

Q. All right. Do you have any reason to disagree with the person from UDL --

A. Absolutely not.

Q. -- who did this?

A. Absolutely not.

Q. The last sentence says, "Overall both strengths of this product have shown no remarkable stability data through the assigned expiration date in the unit dose package."

Do you have any reason to disagree with that?

A. Not at all.

Q. Now, I've shown you -- We know that Actavis tested all this and it was within spec when they tested it. And I've now shown you Quantic batch record review materials. I've shown you FDA testing of the product. I've shown you testing done at the request of UDL; correct?

A. Uh-huh; yes, sir.

Q. We've spent about an hour just going over testing of Digitek; right?

A. Yes, sir.
Q. Do you have any evidence, any documents, any test results to indicate that there was Digitek in the hands of consumers that was outside its labeled specifications?
MR. MILLER: Object to form.
A. Nothing other than the Batch 70924A.
Q. All right. Do you have any evidence that any tablets from --
MR. MORIARTY: Let me withdraw that.
Q. Do you have any evidence that out-of-specification tablets from Batch 70924A made it to the hands of consumers?
A. The batch was tested according to the C of A. According to the certificate of analysis, the batch met requirements. So the answer is: That batch met requirements, yes.
Q. Okay. Well, that batch was -- the investigation of that batch was for double-thick tablets; correct?
A. That's correct, sir.
Q. Not for tablets of normal size with varying potency; right?
A. That's correct.
Q. Do you have any evidence from any document

you have seen, any deposition testimony you have seen, that an oversized tablet from Batch 70924A made it to the hands of a consumer?

A. I would have to say no.

Q. All right.

MR. MORIARTY: That's a good time for a lunch break.

THE VIDEOGRAPHER: Please stand by. We are going off the record. The time is 12:29 p.m. This is the end of Tape Number 3.

(The luncheon recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 1:38 p.m. This is the beginning of Tape Number 4.

Q. Dr. Somma, have you ever consulted with my client, Actavis?

A. No, sir.

Q. Have you ever consulted with Mylan?

A. No, sir.

Q. Now, earlier I went through all that 484 testing from the FDA, and by my count, seven of the batches that they tested are what wound up being the recall batches. Okay? Which is about 4.6 percent.

A. Yes, sir.
Q. Do you have an opinion as to whether that is a statistically significant number?
MR. MILLER: Object to form.
A. Is that statistically significant, the batches that were recalled; correct, Matt?
Q. Yes. Seven out of 152?
A. Whether it is statistically significant or not, it's hard for me to say. Is it representative of what was made? I don't think so.
Q. Why isn't it representative of what was made?
A. Well, to get back to what I had said before, bottom line on all of this was: I have not seen an investigation which resolved the root cause of the things I observed in these other batches, such as some of the blend uniformity issues, things like that.
Other than that, based on the merit and the information in front of me, those are -- those batches passed, yes. And they were confirmed by two -- two sources.
Q. And by my count Celsis, one way or another, tested 11 out of 152 batches, which is about 7.2 percent. Is that statistically significant?
MR. MILLER: Object to form.
A. I would say the same answer again, you know.

Q. And if you add those two together and take out any duplicates that may have been tested by both Celsis and FDA, it's 16 out of the 152, which is ten and a half percent.

Is that statistically significant?

MR. MILLER: Object to form.

A. It's hard for me to answer that question yes or no.

Q. Do you think that FDA's testing seven out of 152 recall batches provides a high degree of assurance --

A. No more than any -- I'm sorry.

Q. -- that those seven batches at least met their specifications for identity, purity, and potency?

MR. MILLER: Object to form. .

A. No. Again, those seven batches -- no more does that testing or Celsis's testing represent the fact that all of the batches in question don't have some problem. It meant that that sample using those specifications at that time met requirements.

It gets back to the point I made earlier: That this is a totality, it's a continuum, it's not just a speck in the results.

Q. All right. Well, have you seen any FDA

documents that someone said that there was a total failure of the quality system?

A. I believe in this Exhibit 26, Matt, there is a statement. I don't know if it says "total failure."

(A discussion is held off the record.)

A. I'm referring to Exhibit Number 26 in response to Matt's question. That was the only -- this is the point that I had seen. That was a comment from the FDA, as far as their quality system goes.

Q. Well, if somebody else were to have said there was a total failure of Quality, do you think that's an overstatement, given the fact that UDL and Celsis have independently confirmed that at least those batches, when tested, met the specifications?

MR. MILLER: Object to form.

A. Again, my -- my --

Q. That one's a yes or no. Do you think it's an overstatement?

A. No.

Q. Explain your answer.

A. I think that statement is based upon what I say the whole picture, not just a series of specifications -- a series of batch results. This speaks to things in total, and that gets back to my comments about investigations and analysis of other

mitigating circumstances.

Q. Well, you know there was an all-products recall a month or two after the Digitek recall; correct? Do you know that?

A. All products were recalled, yes, sir.

Q. And do you know those were not to the consumer level?

A. That I didn't know, sir.

Q. Did you think when you got here today that all the products were recalled to the consumer level?

A. No, no, sir.

Q. You didn't give it any thought one way or another?

MR. MILLER: Object to form.

A. Not that it was pertinent to what I was looking at in this particular case.

Q. Okay. Did the FDA ever make a specific finding in any document that you've ever seen that Digitek was adulterated?

MR. MILLER: Object to form.

A. Well, getting back to the question -- to the definition of "adulterated," I would say, based on the broad-based comment in Citation 1, that based on their definition, those -- Digitek would be adulterated by their definition.

Q. That's not what I asked you.
A. Okay. Then please ask again.
Q. Did they make an explicit statement anywhere that Digitek was adulterated?
A. And, again, I just think if it is noncompliance, by their definition it is adulterated.
Q. I want you to find me a statement in any of the paper in front of you that says -- from the FDA, that Digitek was adulterated. Explicit statement. Not you inferring or --
A. Understood.
MR. MILLER: I'm going to object to form.
A. I'm looking at this Exhibit 91, Matt. And to answer your question point on about they say it's adulterated, this is -- in this particular statement here, it doesn't come right out and say that, "adulterated," it does not say that. Okay?
Q. Okay. Have you seen any FDA statement at all specifically finding that there was out-of-specification Digitek in the hands of a consumer between 2004 and 2008?
A. I think the field action that recalled the batches speak to that point, or not? Did I misunderstand that? By recalling of batches, isn't that what that means, that they thought that that

happened?

Q. Sir, I thought you told me a number of hours ago that you could recall batches of pharmaceutical product for a number of different reasons; correct?

A. Yes, you can, right.

Q. And defective, actual out-of-spec tablets in the hands of consumers may or not be the case; right?

MR. MILLER: Object to form.

A. May or may not be the case, correct.

Q. FDA could recall pharmaceutical products because the label was on crooked?

A. That's correct.

Q. Or they didn't like the way the plumbing in the plant was; correct?

A. That's correct.

Q. All right. So what I'm asking you: In all the ocean of material that you have reviewed, do you find any explicit statement by the FDA that there was out-of-specification Digitek in the hands of consumers between 2004 and the spring of 2008?

MR. MILLER: Object.

A. And, again, to that, Matt, what I would have to answer is that they found noncompliance to procedures, they found information about blend uniformity. Nothing that specifically speaks to

defective tablets being distributed.

Q. And just because there were some blend uniformity out of specs that were the subject of an FDA 483 because of the investigation technique, does not mean there was out-of-spec Digitek in the hands of consumers; does there?

MR. MILLER: Object to form.

A. That's hard to say, Matt, because they never did the investigation as I would have understood it, to be perfectly honest.

Q. All right. But you have all this information available, and you haven't seen any evidence of out-of-spec Digitek in the hands of a consumer; have you?

MR. MILLER: Object to form.

Q. You told me that before lunch?

A. Right, right.

Q. Every piece of evidence you have seen regarding testing of Digitek has been within compliance?

A. Testing -- Absolutely.

Q. Do you have any idea of what percentage of pharmacies in the United States still count out tablets by hand?

A. Oh, I practiced pharmacy for awhile and every

one that I worked in, we counted by hand. So my guess would be -- the big box stores, whatever percentage they are, counting automatically. That would be my guess.

Q. How does a big box store go from a thousand-count bottle of tablets on a shelf into a vial with an automatic counter? Or are you talking about mail order pharmacies?

A. No, sir. They would fill a tablet counter up with a thousand tablets, type in the number they need --

(A discussion is held off the record.)

A. Set the counter and then the machine counts the tablets.

Q. And what percentage of pharmacies in the United States use automated versus hand counting?

MR. MILLER: Object to form.

A. That would be a complete guess on my part. It's got to be a small percentage.

Q. You mean it's a small percentage that use automatic?

A. Yes, sir.

Q. So if tablets were out of specification by size, that's what's known in the industry as a visible defect; is it not?

A. Visible -- visual defect, yes.
Q. And it is at least theoretically possible that the pharmacy level, when tablets are hand counted, is a point at which tablets that were extra thick could be detected; correct?
MR. MILLER: Object to form.
A. I would have to agree to an extent; but saying, based on my pharmacist's background, I was not looking for thick tablets. My objective was to make sure that the prescription was filled adequately, that the all -- that all of the paperwork was filled out, and that the clinical profile of the patient was done. And a lot of cases nowadays, it is done by a technician.
Q. All right. Well, some human being was used to counting out tablets; right?
A. Right.
Q. Have you ever actually seen and touched a Digitek tablet?
A. No, sir.
Q. I'm sorry?
A. No, sir.
Q. If a tablet that was supposed to be between two and three millimeters was double thick, so it was somewhere between four and six, is that a visual

defect that a reasonable technician or pharmacist would be able to detect when counting out a prescription of 30 to 100 tablets?

MR. MILLER: Object to form.

A. I don't think so, because when you put these into a counting tray, they all lay down flat. How would you able to determine -- determining height of tablets, Matt, across a bed of tablets is very difficult. You would actually have -- it would have to be on your side.

So my guess is that that's pretty tough to do, just from having done it myself.

Q. Well, if there was one double-thick tablet in there, it would be sticking out like a skyscraper, right?

A. Like a skyscraper, yeah. That you -- Unless you -- in that case, if it was that thick. But again, three millimeters, double, six; my guess is you probably would see that.

Q. All right.

A. I'm not saying I would see that.

Q. Did you say earlier you had not reviewed any adverse event reporting data in this case?

A. That's correct.

Q. Do you have any opinions about adverse events

with Digitek?

A. No, sir.

Q. Did you ask Mr. Miller or Ms. Carter how many of the plaintiffs in this litigation had had their tablets weighed or measured?

A. No, sir. I looked for the information in the information provided.

Q. All right. You didn't see any plaintiffs who had double-thick tablets; did you? Or even extra-thick tablets?

A. I didn't see -- I didn't see any information that said that at all. Okay?

Q. In a piece of litigation like this, and I know you are new to this process, but if they had evidence that their clients had extra-thick tablets that were outside the specifications, do you think it's the kind of material that they would give you to review?

A. I would think so.

Q. Have you seen any reliable reports that an extra-thick tablet was detected by a pharmacist in 2005, 2006, 2007 or 2008?

A. We had discussed that before, as I recall. I thought I did, but I was not able to recover it.

Q. Well, I said reliable report by a pharmacist

of an extra-thick tablet in 2005, '06, '07 or '08.

MR. MILLER: I'll object to form.

A. We just -- I'm going to look again.

I read it, Matt, and I cannot find it.

Q. You believe you have a report, a reliable report from a pharmacist that indicates that they found a double-thick tablet in the years I just mentioned, '05 through '08?

A. As I recall, the report was about a pharmacist finding a tablet, and the year I believe was '04.

Q. Is that the one -- Well, wait a minute. I said '05 through '08 three times.

Do you have such a report?

A. That's -- as I'm trying to think through it, I cannot locate it here.

Q. Do you think there is one? Now, we discussed one this morning about this nursing home, and you told me that it wouldn't be reliable given everything I asked you about it.

A. Right, right.

Q. I'm asking about a different question. A reliable report from a pharmacist in 2005, '06, '07 or '08 indicating that they had an extra-thick Digitek tablet.

MR. MILLER: Object to form.

A. Nothing that I can produce, no, sir.

Q. Can you look for Exhibit 21 in the stack, also known as Plaintiff's Exhibit 128?

Have you seen this document before?

A. Yes, sir.

Q. This is the extra-thick tablet investigation. The investigation was conducted in 2004; correct?

A. Yes, sir.

Q. And you see in here that somehow Actavis or Amide at the time was able to figure out that that came from a batch made in 2003; correct?

A. Yes, sir.

Q. Did the company alert the FDA to this event through what's known as a field alert report?

A. I don't know, Matt.

Q. Okay. I'd like you to look at Exhibit 20. It should be in that stack.

Have you seen that document before?

A. I believe so.

Q. It's an EIR from 2004. Is that correct?

A. Yes, sir.

Q. I'd like you to go to Page 4, please.

A. Uh-huh.

Q. Now, first of all, in order to be operating

under a consent degree -- decree, do you have to be in compliance with cGMPs?

A. Absolutely. You have to be in compliance with cPMG's if you make a product that's subject to human consumption.

Q. All right. So in the first paragraph, under "History of Business Operations" --

A. Right.

Q. -- four lines down, there is a sentence that says, "The consent decree was lifted in 2001 following successful demonstration of sustained cGMP compliance."

Do you see that?

A. Yes, sir.

Q. Do you have any reason to disagree with the FDA about that?

A. No, sir.

Q. Let's go to Page 6. Under the Field Alert Reporting section.

A. Uh-huh.

Q. It says, "A final field alert report for NDA 40-282, digoxin tablets .25 milligrams was filed during the reporting period."

Do you see that?

A. Yes, sir.

Q. And if you read on, what they're referring to is the investigation contained in Exhibit 21. Is that right?

MR. MILLER: Take your time and read it.

A. Got it. Okay.

Q. Am I right?

A. Yes, sir.

Q. So go down ten lines from the top of that paragraph. It says, "No additional complaints or reports of thick tablets have been received for this high volume product."

Do you have any reason to disagree with the FDA about that?

A. I don't see why, no.

Q. Okay. "The event was considered an isolated incident and corrective actions were put in place to prevent its reoccurrence."

Do you agree with that?

A. Uh-huh, yes, sir.

Q. Now let's go to Page 9. In the section called Complaints, the second paragraph.

It says, "A larger number of complaints was also noted for digoxin tablets; however, it is the highest volume product according to the list of batches produced per year."

Do you have any reason to disagree with that?

A. No, sir.

Q. "There were also no trends observed for the types of complaints."

Any reason to disagree with that?

A. No, not at all.

Q. Was FDA satisfied with the investigation of Exhibit -- that's embodied in Exhibit 21?

MR. MILLER: Object to form.

A. Let me just change my glasses.

Based on the data I have in front of me, they're satisfied, yeah.

Q. There was never a 483 or a warning letter about that incident or its investigation; is that correct?

A. I'm just making sure this 483 is not it. This one, I'm just looking at one from May back. No. The answer is: There is nothing as a result of this.

Q. All right. Now, before the lunch break you told me you didn't have any evidence of out-of-spec tablets getting in the hands of consumers. I want to talk a little bit more about that. Okay?

A. Yes, sir.

Q. Do you have an opinion --

MR. MORIARTY: Withdraw that.

Q. Let me start over. Let's just talk about the recalled batches, and let's assume there were 688.2 million tablets in that grouping; okay?

A. Okay.

Q. Do you have an opinion to a probability as to how many of them were outside their specifications?

A. I think when we discussed, we said that none of those that were released were out of specification, as I recall. The probability of -- of them being out of specification, which means tablets which were not tested, in other words a batch is made of two million, you test 100. So the probability of one that is not tested sneaking out is within the realm of possibility, yes.

Q. Okay. Do you know that -- in your work at Novartis, I assume you talked to scientists, people all the time; right?

A. Right, okay.

Q. You are familiar with the terms "probability" and "possibility;" right?

A. Right, everything is possible, correct.

Q. And probability is more likely than not; correct?

A. It's probable, it's likely.

Q. Okay. So what I'm trying to find out, and my

clients are entitled to know, is whether you have an opinion to a reasonable probability as to how many of the 688 million tablets among the recalled group were outside their specifications? Do you have such an opinion?

A. I have an opinion based on a review of the information I've seen.

Q. Is it an opinion to a probability?

A. To a probability? Based on the information I've seen, and the lack of investigation and rigor that addressed the problem, that it is highly probable that something was distributed and not caught; caught in the testing sense.

Q. Okay. How many of the 688 million tablets in the recall group were likely outside their specifications?

A. That's very difficult to say.

Q. You have no opinion to a probability as to a number?

A. I think it's hard to put a number on it, to be perfectly honest, because what we are talking about in this particular case, my opinion is they did not do a rigorous enough evaluation of things to assess that they even had a problem. In that case, the probability could be as high as 100 percent and could

be as low as zero. Without the analysis and the information to make that assessment, Matt, I can't say for sure.

Q. All right. So you would be speculating to put a number; right?

A. I think that would be a safe bet, yeah.

Q. Okay. So -- And I can keep -- I'm going to keep asking you these questions, because I need to know, not because I'm trying to be a pain in the neck.

But if a tablet was outside its specifications, there are only two possibilities there; one is it's high outside the specs or low outside the specs; correct?

MR. MILLER: Object to form.

A. Correct. Okay.

Q. Are there any other possibilities besides -- if they're outside the specs, are there any other possibilities besides high or low?

MR. MILLER: Object to form.

Q. Answer me as a scientist.

A. As a -- if there were -- they're either outside the spec, high, or low outside the spec, correct, correct. There's a range.

Q. Okay. All right.

Ignore the man outside the curtain for right

now.

MR. MILLER: Do not ignore the man outside the curtain. Disregard that.

MR. MORIARTY: Behind the curtain, I should say.

Q. So do you have any opinion to a probability as to how many of the recalled Digitek tablets were outside the specifications, low?

A. I would have --

MR. MILLER: Excuse me. I'm going to object to the form.

Q. On the low side?

A. I would -- it's -- again, I'm not trying to be evasive. It's just difficult to answer that as if on the high side. The question is -- I can't -- I can't assign a number to that.

Q. All right. My first question was: Did you have an opinion as to whether they were outside the specs as all, and we covered that.

A. Yes, we did.

Q. Now I'm getting into the two possibilities.

A. Right.

Q. And if you don't have an opinion to a reasonable probability, that's all you have to tell me.

A. Okay.
Q. So you don't have an opinion to a probability of how many were outside the specifications on the low side; correct?
A. No, sir.
MR. MILLER: Object to form.
Q. Do you have an opinion to a reasonable probability how many were outside the specifications on the high side?
A. No, sir.
Q. And it matters how low or how high; correct?
MR. MILLER: Object to form.
A. With --
Q. I'll rephrase my question.
If you were doing an investigation for a pharmaceutical company --
A. Right.
Q. -- whether it was Novartis or one of your consulting clients, and they had been releasing product that was outside the specifications, would you as a scientist want to know how far outside the specs they were?
MR. MILLER: Object to form.
A. Well, I think -- let me make sure I --
Q. Yes or no. Would you want to know that?

A. I wouldn't expect them to release anything outside of spec.

Q. That's not what I'm asking. You were called in as a consultant and somebody says, "We accidentally made some tablets that were outside the specs."

A. Oh, okay.

Q. It's a done deal; okay?

A. Right.

Q. You are called in as the consultant to do an investigation. Do you as a professional want to know how far outside the specs they were?

A. You have to do an analysis for trend, is it high, or is it low, yes.

Q. So do you have an opinion -- if there were by chance any tablets outside the specifications low, do you have any opinion as to how low outside the specs they were?

MR. MILLER: Object to form.

Q. To a probability?

A. Not until I see the information, I guess. It's hard to say, you know.

Q. Okay. But you haven't seen any such information about tablets outside the specs at all; correct?

MR. MILLER: Object to form.

A. In this particular case, no. They have -- in other words, I have asked for the information. I haven't seen any of that information, right.

Q. On the other side, do you have any opinion to a probability as to how far outside the specs high any Digitek tablets might have been, if there were any?

MR. MILLER: Object to form.

A. No, for the same reason I couldn't understand on the low side.

MR. MORIARTY: What's the basis for your form objection? I want the chance to cure it.

MR. MILLER: It's vague and misleading. Perhaps the expert does, but I don't know what specifications you were asking about.

Q. Outside any specification: Weight, thickness, active pharmaceutical ingredient. Did you understand my questions?

A. Yes.

Q. Okay.

A. To be real -- I want to-- that's my -- I understand what you are talking about. It doesn't matter -- A spec is a spec. I apologize.

Am I supposed to have clarified that?

Q. No. You and I understood one another perfectly. Okay.

Now, I assume, Dr. Somma, from reading your report and listening to what you are saying today that because of some cGMP violations, you have concerns about Digitek production. Am I correct about that?

MR. MILLER: Object to form.

A. There are -- the concerns I have are the --

Q. Yes or no?

A. Yes.

Q. Do you have concerns?

A. Yes, I do. Oh, I'm sorry. Yes, I do.

Q. And from a regulatory standpoint, when you are looking from the cGMP standpoint, there are findings in the FDA -- these FDA documents that lead you to conclude, and led the FDA to conclude, that Digitek may have been adulterated. Is that correct?

MR. MILLER: Object to form.

A. Yes.

Q. All right. But as we covered before, "adulterated" does not necessarily mean that the tablets were, in fact, outside their manufacturing specifications. Is that right?

MR. MILLER: Object to form.

A. "Adulterated" means -- could mean things that are major-major or minor, yes; not outside the specifications.

Q. So when we get specifically to Digitek, and I'll talk about the recall in more detail in a minute; FDA would have every right to ask Actavis to recall the Digitek within the expiration date just because they believed the investigation of 70924 was substandard. Is that right?

MR. MILLER: Object to form.

A. That's certainly within their right, yes.

Q. Even if there was no proof whatsoever that actually out-of-spec tablets made it to pharmacies and consumers. Is that right?

MR. MILLER: Object to form.

A. Could we go through that one more time, Matt? I'm not trying to be stupid.

THE WITNESS: Can I have that question again, Mark?

MR. MORIARTY: Mark, you are going to have to read that last one back.

(The question is read.)

A. Yes.

Q. So if I ask you a different way, do you have an opinion to a reasonable probability how many Digitek prescriptions were filled which contained as low as one out-of-specification tablet? Do you have an opinion to a probability on that subject?

A. That would fall -- that falls back into: Is it going to be low or is it going to be high. I guess my opinion is it's likely that something could be there. As far as a percentage, Matt, no.

Q. Now, wait.

A. Run it by me again.

Q. All along you have told me you have no opinion to a probability, this is what I'm hearing from you. Okay?

A. Right.

Q. Maybe Peter hears it differently.

A. Right.

Q. I'm hearing you have no opinion to a probability, a likelihood, that there were defective tablets in the hands of consumers at all?

A. Right.

MR. MILLER: Object to form. Misstates previous testimony.

Q. So I'm asking it from a different angle to make sure I have it all straight.

Do you have an opinion to a probability about how many people received any prescriptions with any defective, outside-of-specification Digitek tablets in them?

(A discussion is held off the record.)

A. No. I was still thinking about the spec thing, sorry.

Q. If there were tablets outside the specifications -- Okay? -- and let's just assume for right now that they were extra thick, and that because they were extra thick, they were outside the API specs on the high side. Okay? Let's just make that assumption for right now.

A. Okay.

Q. All right? If that were true and they went out into the marketplace, wouldn't it be likely at some point that collectively a pharmacist, a consumer, UDL, Actavis, FDA, Celsis Labs, a doctor or a hospital would notice something?

A. That's --

MR. MILLER: Object to form.

Sorry. Go ahead.

A. That's assuming that those systems are not set up to be challenged to find defects. Your system itself is supposed to be self-limiting, and your supply chain and distribution aspects are not meant to catch problems. Pharmacists and professionals in the distribution chain, if you are lucky, they are going to be vigilant and catch it. Have they been calibrated or are they checked?

You can't rely on that, is my opinion.
Q. I'm not asking you, Doctor -- or Dr. Somma, if you rely on that prospectively.
A. Right.
Q. I'm asking: After the fact; okay? Again, let's get back in. You are at Novartis and you have been called in --
A. Right.
Q. -- to one of your pharmaceutical clients. And somebody says, "I think we may have released tablets that are too thick, and if they are too thick they may have been outside the API specs;" okay?
A. Right.
Q. There are things to look at once the tablets leave your facility to see if, in fact, there were out-of-specification tablets; right?
A. These are --
Q. Yes or no? Things you can look at.
A. Things that you can look at, yes.
Q. All right. So one thing you might look at is: Did a repackager find any. Right?
A. Right.
Q. That's one thing you might look at.
A. Right, yes.
Q. And FDA tested tablets. Did they find any?

A. Right.
MR. MILLER: Object to form.
Q. And pharmacists would be counting these out and distributing them; did they find any? Correct?
A. Correct.
Q. You are continuing your investigation; right?
A. Right.
Q. You are nodding yes?
A. Yes, I'm hearing you. Sorry.
Q. And then, of course, consumers get them; and they could either notice it because it looked different than other tablets --
A. Yes.
Q. -- or they might get sick; right?
A. Well, we have assumed they would get sick, yes.
Q. But these are things that a reasonable investigator would look at; right?
A. Uh-huh.
Q. Is that yes?
A. I would ask the questions, and to be perfectly honest, I probably wouldn't go beyond asking this Celsis and the packager. I mean, I'm -- in my opinion -- my personal opinion, that's reaching when you try to rely on pharmacists as I had mentioned

before. But I'm okay with you right out into the packaging part, yeah.

Q. But if you are desperately seeking information, any shred of proof, you would want to go all the way to the consumers; wouldn't you?

A. Yes, sir.

Q. You might look at Poison Center statistics to see if they'd noticed a spike in digoxin toxicity?

MR. MILLER: Objection to form.

Q. Would you do that?

A. It sounds like a great idea. I would not have thought to do that, yes.

MR. MORIARTY: What was the matter with the form on that?

MR. MILLER: Scope. Excuse me. Objection, scope.

Q. Could you look for Exhibit 37, please?

Now, I am missing an exhibit, I think. Somewhere in this should be the recall press release.

Have you ever seen the recall press release of Digitek?

MR. MILLER: It's not that document. He pointed that document out, but that's not the document.

Q. I'll get to this one in a minute.

But have you seen the recall press recess of Digitek?

A. I don't recall reading it, Matt, no.

Q. What is your understanding of why Digitek --

I'm sorry. Let me rephrase that.

What is your understanding of what the FDA approved recall notice says about why Digitek was recalled?

MR. MILLER: Object to form.

THE WITNESS: Mark, read that question to me again, would you? If you don't mind.

Is it okay? I'm sorry.

(A discussion is held off the record.)

(The question is read.)

MR. MILLER: Again, object.

A. I haven't seen it, so I don't -- I can't really say.

Q. Okay. Here's Exhibit 36. It's the recall press release. I want you to take a look at that, and then if you don't mind, hand it back to me.

A. Sure thing.

Q. Because I seem to have coughed up all my copies of it.

Are you done reading it?

A. Yes, sir.

Q. May I have that back, please?
A. Sure. Here you go.
Q. It says here, "The voluntary all-lot recall is due to the --"
MR. MILLER: I was trying to have a copy in front of him so he can read along with you.
MR. MORIARTY: Oh, that's fine. I appreciate it.
Q. "The voluntary all-lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released."
Do you see that?
A. Yes, sir.
Q. Do you have any reason to disagree with that FDA-approved press release?
A. No, sir.
Q. And twice in that sentence that I just read, they use words connoting some degree of speculation. Is that right?
MR. MILLER: Object to form.
A. Yeah. "Possibility," "may have," yeah.
Q. Now, you can take a look at Exhibit 37.
A. Okay.
Q. Go to the third page. This is the recall package. Do you know what a recall package is?

A. I'm not familiar with all its content. I've heard of it.

Q. Have you ever seen this document before, Exhibit 37?

A. In the -- In the spirit of what I investigated, Matt, I didn't look at stuff -- this stuff, like the recall package. I didn't look at that.

Q. Did you look at Exhibit 36, the recall press release?

A. No, sir.

Q. If you go down to "Reason For Recall" in Roman numeral III, it says, "Digoxin tablets exceeded the thickness specifications."

Do you see that?

A. Okay. Yeah. I got it.

Q. Now, have you seen anywhere at all any indication from FDA or from my client, Actavis, that this recall of Digitek in April of 2008 was for normal-sized tablets with varying amounts of the active pharmaceutical ingredient?

A. This clearly notes "tablet thickness."

Q. Now, I'm done asking you about that.

If you were called in as you were with one of your private consulting clients to analyze a thick

tablet situation --

A. Yes, sir.

Q. -- typically you would think that that would be a tablet press issue. Is that right?

A. You'd want to -- you'd want to start at that point. It's the most likely.

Q. Okay.

A. Yes.

Q. And when you are looking for the cause of the extra-thick tablets, what you hope to get to is what you in the business call a root cause; right?

A. That's correct.

Q. So for a wild example, it could be a die set inappropriately calibrated; right?

A. Agreed.

Q. Okay. And that is --

Now, a normal-sized tablet with varying active pharmaceutical ingredient is a different or potentially different problem; isn't it?

A. Absolutely.

Q. So when you start looking for a root cause to that kind of problem, you have to go back to the mixing, the blending, the tabletting? You have to go back to all of it; correct?

A. The non-homogeneity in a tablet, yes, Matt.

Q. And extra thick tablets and tablets of normal size with varying potency are really, when you get down to it, from a professional's end, different kinds of defects. Is that right?

A. I see them -- this is why -- it's not going to be yes or no.

If the thing was uniform, the thick tablet and non-uniform tablet, that problem is one and the same, because that thickness is going to be more potent, let potent. We don't know that in this particular case. In this particular case that is thick, but we don't know why or how much.

So the answer is -- to answer your question specifically, there are two different cases here.

Q. Okay. And the FDA would know the difference between those kind of problems; right?

A. You would hope.

Q. You would hope.

A. Okay.

Q. And so when the FDA approved the recall press release and the recall package announcing that this recall was for the possibility that double-thick tablets may have been commercially released, it has a little bit more meaning just beyond those simple words; correct?

A. Presumably --
MR. MILLER: Object to the form.
MS. CARTER: Object to the form.
A. To me it does, yes.
Q. Okay. To you as a professional in the pharmaceutical industry, it does?
A. Right. That's what I'm saying.
Q. And as far as you can tell from all the material here, FDA did not cite or warn Actavis about Digitek that was normal in size, but outside its active pharmaceutical ingredients specifications. Is that right?
MR. MILLER: Object to form.
A. Yeah, Digitek tablets, no. The only thing was blend stuff that we talked about before.
Q. All right. Did the FDA ever ask Actavis to recall Digitek for blend uniformity issues?
A. Not to my knowledge, no.
Q. I want to show you what's been marked as Exhibit 38.
A. Okay.
Q. Have you ever seen this before?
A. It doesn't look familiar.
Q. It's a printout from the FDA's website.
A. Okay. I'm not a -- I don't customarily go

there and read stuff like this. I'm sorry. Okay?

Q. Okay.

A. Yeah.

Q. Well, once you were engaged in the Digitek litigation --

(A discussion is held off the record.)

Q. Once you were engaged in the Digitek litigation, even though you didn't customarily go to the FDA's website, did you do so to see what they said about the Digitek --

A. No, sir.

Q. -- recall?

A. No, sir. I went there to make sure that I had as much information as I needed about guidances in the area of uniformity.

Q. Okay. This is from a section of the FDA website that talks about facts and myths about generic drugs. Do you see that at the top?

A. Yes, sir.

Q. And then generally it has a fact --

MR. MORIARTY: I'm sorry. I'm going to withdraw that question.

Q. And if you look about halfway down, what FDA does here is they put a myth, and then they follow it up with a fact; correct?

A. Right.
Q. Go to the second page, please. The first bolded myth at the top says, "There are quality problems with generic drug manufacturing. A recent recall of generic digoxin called Digitek shows that generic drugs put patients at risk."
Do you see that?
A. Uh-huh.
Q. And then the FDA follows up with the fact.
"FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs, generic and brand name, are held."
Do you see that?
A. Yeah.
Q. Now, let's go down to Bullet Point 4.
A. Right.
Q. The second sentence says, "In our best judgement, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely."
Do you see that?
A. Uh-huh.
Q. That's a yes?
A. Yes, I see it.

Q. Do you have any reason to disagree with FDA's statement about this situation?

A. I don't think so.

MR. MILLER: Objection. Scope.

Go ahead.

A. Yeah, I think so. Otherwise why would we be having this discussion here?

Q. Well, that's a really good question.

Did you do a more thorough investigation than the FDA?

MS. CARTER: Object to form.

A. I did an investigation based on the information provided to me for this product, yes. Did I do more than FDA? No.

Q. All right. Well, what's the basis for your disagreement with the FDA's statement on its own website regarding this very situation?

A. Well, I don't think the necessary investigation into the manufacturing -- in the manufacturing area was conducted. That is still my opinion.

Q. I understand that.

A. Oh, okay.

Q. But FDA doesn't say anything about the investigation of 70924; does it?

MR. MILLER: Object to form.
Q. In this document?
A. No, sir, it doesn't.
Q. Okay. It's commenting on the situation overall?
A. Uh-huh.
Q. And clearly, FDA knew about the investigation of 70924 because they put it in -- in a 483; right?
A. Right.
Q. So let me get back to this and make sure I understand. It says, "In our best judgement given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely."
Do you have any reason to disagree with FDA in that statement?
MR. MILLER: Object to form. Asked and answered.
A. No. There is no reason to disagree with this.
Q. Okay. Is it your opinion that the investigation conducted by Actavis of the double-thick tablets in Batch 70924 was a cGMP failure?
MR. MILLER: I'll object to form.

MR. MORIARTY: Even when I ask you questions in your favor, you object.

Q. Go ahead.

A. I think that it was conducted in a way that it was aligned with cGMP. Was it conducted to what I would consider an adequate level? No.

Q. Was it negligent?

MR. MILLER: Object to form.

MS. CARTER: Object to form.

A. Was it negligent? Insofar as all the information wasn't there that I was looking for, I don't think it's negligence, but it certainly was not with the rigor that I would have expected.

Q. And that's your opinion?

A. That is my opinion, yes.

Q. Okay. Is there any specific FDA reg that says you need to -- you are required to analyze the batch before and the batch after in the course of an investigation like this?

MR. MILLER: Object to form.

A. I think it comes -- what it does, Matt, is it's customarily done. Is there a regulation that says you must do that? That's where business, science and regulations cross paths.

Q. All right. And the answer is?

A. I don't think -- I could sit here and look it up. I don't think you would ever find something that says that specifically.

Q. All right. In the course of your investigation in this litigation, did you look at the last Digitek batch which precedes -- batch record for the batch which preceded 70924?

A. I got a batch record that was close. That was the one I had mentioned earlier. That was the best I could do.

Q. And did you also look at one following close after 70924?

A. Not to date, no, sir.

Q. Have you asked for one?

A. Yes, sir. I haven't read it.

Q. Okay. Did you find any problems in the batch record for the batch that preceded 70924?

A. Preceded? Based on that one?

Q. Yeah.

A. Batch record? No, no, sir.

Q. So if Actavis would have looked at the batch record for the batch preceding 70924 in the course of the actual investigation, it wouldn't have found anything either; right?

MS. CARTER: Object to form.

A. My -- my guess, no. Because that's all part of rounding up the information. That's the first step.

Q. I'd like you to go to your report, please, which is --

MR. MORIARTY: Is it Exhibit 52?

MR. MILLER: Yes, it is.

Q. Your report is 14 pages long; right?

A. Yeah, yes, it is.

Q. Does the word "negligent" appear anywhere in these 14 pages?

A. Negligent? No, sir, I don't recall using that.

Q. Does the word "adulterated" appear anywhere in these 14 pages?

A. No, sir.

Q. Does the word "defective" appear anywhere in these 14 pages?

A. I don't recall.

Q. Okay. Let's go to Page 2. You comment under "Blending" that this is a dry blend direct compression process; correct?

A. That's right.

Q. Relatively speaking, is that a rather simple, solid oral dose formulation?